UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,277	05/22/2000	Roger K. Cady	57294-012	1639

7590 09/08/2005

Husch & Eppenberger LLC
401 Main Street
Suite 1400
Peoria, IL 61602

EXAMINER
KIM, VICKIE Y

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/575,277	CADY ET AL.	
	Examiner	Art Unit	
	Vickie Kim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-27,31,32,43,44 and 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04-2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment and terminal disclaimer filed 9/30/2004.

2. Upon entering the amendment, the claim 20 is amended and the claims 28-30, 33-42, 45-54 are canceled.

New claims 55 are added.

3. The claims 17-27, 31-32, 43-44 and 55 are pending and presented for the examination.

Claim Rejections - 35 USC § 112, 1st

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

2. Claims 17-27, 31-32, 43-44 and 55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is only enabled for a method of reducing occurrence of headache or treating headache, but not enabling for complete prevention of headache. Thus, complete prevention of all types of headache is not commensurated in the scope with the said claims.

The specification is only enabled for a method of reducing occurrence of headache or treating headache using certain antimigrain medication such as 5ht1 agonist , but not enabling for complete prevention of headache using any antimigrain medication. Thus, complete prevention of all types of headache is not commensurated in the scope with the said claims.

Attention is directed to In re Wands, 8 USPQ 1400 (CAFC 1988) at 1404 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls) at 547 the court recited eight factors:

1) *The nature of the invention:*

The instant invention is related to preemptive prophylaxis of heahache using antimigrain medication such as 5HT1 agonist.

2) *The state of the prior art:*

The state of art does not recognizes that headache can be completely prevented by any single drug therapy. Because there are numerous class of headache(e.g. cluster headache, migraine, etc) and also all possible patho-etiologies responsible for each headache are not completed understood, and furthermore, headache involves more than biological mechanisms for developing such conditions, it is impossible to be completely prevented.

Generally, art acknowledges that the headache(pain) can be reduced or treated but not completed prevented or inhibited because all the possible causes are unknown

or completely avoidable. There are no single known compounds of similar structure which have been demonstrated to treat all types of diseases or conditions related headaches or it's manifestations associated with headaches. Since this assertion is contrary to what is known in medicine, proof must be provide that this revolutionary assertion has merits. The existence of such a "silver bullet" is contrary to our present understanding of pharmacology. Especially anti-headache activity is closely related to the dose dependent response, against all types of claimed conditions or disease generally.

3) *The relative skill of those in the art:*

The relative skill of the those in the art is high.

4) *The predictability of the art:*

The high degree of unpredictability in the treatment of headache is well known in the art. The specification does not provide a competent evidence or disclosed tests for all the possible headaches that are highly predictive for the pharmaceutical use as claimed of the instant compound. A slight change in the structure of the drug would drastically change its selectivity for the receptor and its inhibitory activity as evidenced by the structurally very similar compounds.

For the use of a pharmaceutical composition, the efficacy of the composition containing multiple active and inactive ingredients of different chemical structures and modes of actions, their interactions, co-actions, e.g. synergism etc. is extremely unpredictable.

5) *The breadth of the claims:*

Applicant's assertion that the inventive compound would be useful for preventing headaches does not commensurate with the scope of the objective enablement, especially in view of the high degree of unpredictability and the limited working examples.

6) *The amount of guidance/working examples:*

The specification lacks in providing any working examples against complete preventing headache or preemptive prophylaxis purpose. The specification provides few working examples of test to show certain prodromal symptoms and it's relief. These conditions cannot be effective for different headache which has different prodomal symptoms, etc. It is impossible to predict possible outcome with patients with different stress and causative factors, as well as a complex interrelation between nutrition, health, and the different phenotypes of gene in relation to the health of the individual.

With lack of evidentiary support, it is beyond the skill of skilled artisan today to get an agent to be effective against all the claimed conditions and diseases of headache.

The exemplfied test for evaluating the biological activities of the instant composition is not complete to cover different patho-ethiologies and biological mechanisms. Furthermore, the exemplified test does not show complete inhibition or prevention.

The specification only exemplified few antimigraine medication at page 19. No sing drug can represent whole antimigraine medication because each compound would have materially different chemical structures and origins, or utilizes very different

mechanism of action, etc. With lack of evidentiary support, it is beyond the skill of skilled artisan today to expect the same result from any antimigraine medication to be effective against all the claimed conditions and diseases of headache.

7) *Quantitation of undue experimentation.*

Since insufficient teaching and guidance have been provided in the specification, one of ordinary skill in the art, even with high degree of skill, would not be able to make or use the composition as claimed without undue experimentation. Since the efficacy of the claimed compound(e.g. 5HT1 agonist) in prevention of different headache caused by different causative factors can not predicted from a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study " to use the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 17-19, 31-32 and 43-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Plachetka(US6060499 or 6,586,458).

The claims are drawn to a composition and a preemptive prophylaxis migraine method using an antimigraine composition wherein the composition contains $5HT_1$ agonist as active ingredient. Optionally, the preemptive prophylaxis method uses the composition comprising 5HT1 in combination with NSAID such as COX-2 inhibitor.

Plachetka (US'499 or '458 hereafter)teaches a method of treating migraine using a $5HT_1$ agonist such as naratriptan(1-100mg, see column 5) in combination with NSAID(e.g. COX-2 inhibitor), see abstract, claims and col. 7-col.8. US'458 further teaches that the treatment (Plachetka's) provides an initial migraine relief which reduces or abolishes the symptoms from first onset of the precursor indicia of a migraine headache such as the aura and visual "scotoma", see col.8.

It is noted that the aura is a typical prodromal symptom of migraine as evidenced by applicants' own admission, see instant specification page 1, line 30. As clearly evidenced by the teaching of Plachetka's patents, the preemptive prophylaxis migraine method would have been envisaged by the treatment of US'458 which provides the avoidance of migraine by treating precursor symptoms.

Although the terminology used in application and the patent may not be the same, but the function would cover the scope of the claimed invention.

It is well known in the art as evidenced by Levin(US6432986) that teaches the definition of prodromal symptoms of migraine headache including depression, irritability,

restlessness, anorexia, scintillating scotomas, visual changes, paresthesias and hemiparesis, see col.2, lines 58-64.

Thus, all the critical elements required by the instant claims are taught by the cited reference and the claimed subject matter is not patentably distinct.

Double Patenting

2. A terminal disclaimer filed 9/2004 obviate this rejection and thus, double patenting rejection is withdrawn hereinafter.

Conclusion

3. No claim is allowed.

4. During telephonic conversation, applicant is informed and the proposed claims are offered. The proposed claims 55, and 21-27 and 31-32, 43-44 contain proper dependency changes and amending claims from preventive use to reduction of occurrence to obviate the 112 rejection. No agreement is reached.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
September 6, 2005
Art unit 1618